

JAN - 7 2005

**SECTION 2. SUMMARY AND CERTIFICATION****A. 510(k) Summary**

**Submitter:** Nonin Medical, Inc.

**Contact Person:** John R. Dalpee  
Director of Regulatory Affairs  
Nonin Medical, Inc.  
2605 Fernbrook Lane N.  
Plymouth, MN 55447-4755

**Date Prepared:** December 6, 2004

**Trade Name:** Model 4100 Patient Oximeter Module

**Classification Name:  
and Number:** Class II, 21 CFR 870.2700

**Product Code:** 74 DQA

**Predicate Device(s):** Nonin's Model 4100 Patient Oximeter Module is substantially equivalent to the Avant® Model 4000 Pulse Oximetry System manufactured by Nonin Medical, Inc. that was cleared by the FDA under K041156 on 6/09/04.

**Device Description:** Nonin's Model 4100 Bluetooth® - enabled wrist-worn Patient Oximeter Module measures and transmits SpO<sub>2</sub>, pulse rate, and plethysmographic data to a compatible Bluetooth – enabled device. The patient module includes a class II Bluetooth radio with a range of approximately 30 feet (spherical range).

The 4100 Patient Oximeter Module is powered with two AA batteries, which last for approximately 120 hours when used continuously.

**Intended Use:** The Nonin® Bluetooth® - enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), pulse rate, and plethysmographic data to a compatible Bluetooth – enabled device.

**Functional and  
Safety Testing:**

Nonin's Model 4100 Patient Oximeter Module has successfully undergone both bench and clinical testing in order to demonstrate that it has appropriate functional features and is substantially equivalent to the predicate device.

**Conclusion:**

Nonin's Model 4100 Patient Oximeter Module is substantially equivalent to the Avant® Model 4000 Pulse Oximetry System manufactured by Nonin Medical, Inc. and cleared by the FDA under K041156 on 6/09/04.



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. John R. Dalpee  
Director of Regulatory Affairs  
Nonin Medical, Incorporated  
2605 Fernbrook Lane North  
Plymouth, Minnesota 55447-4755

Re: K043359  
Trade/Device Name: Model 4100 Patient Oximeter Module  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA  
Dated: December 6, 2004  
Received: December 17, 2004

Dear Mr. Dalpee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

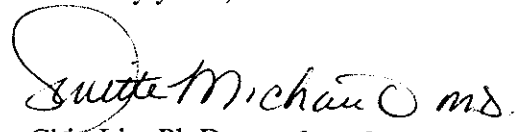
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
Chiu Lin, Ph.D. *for DR. LIN*  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

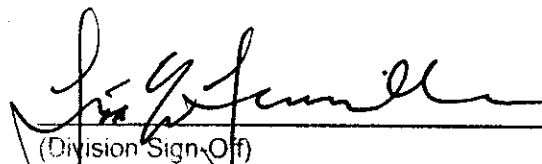
510(K) Number: K043359

Device Name:

Nonin Medical, Inc. Model 4100 Patient Oximeter Module

### Indications for Use:

The Nonin Bluetooth® - enabled Model 4100 Patient Oximeter Module is indicated for use in measuring and transmitting functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), pulse rate, and plethysmographic data to a compatible Bluetooth® - enabled device.

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
DR. CHIU LIN  
01-07-05  
510(k) Number: K043359

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)